

### AMENDMENTS

Claims 1, 8-9, 11-15, and 17 are pending.

Claims 1 and 11-14 have been amended.

Claims 2-7, 10, and 16 have been cancelled.

Support for the amendments is found in the claims and specification (e.g., page 3, ln. 13-18; page 4, ln. 9 to page 5, ln. 10; page 6, ln. 19; page 7, ln. 11-18; page 11, ln. 5-7; and the Examples), as originally filed.

No new matter has have been added.

### REMARKS/ARGUMENTS

Claims 1, 3, and 10-17 are rejected under 35 U.S.C. 103(a) over Yamagishi et al., JP 2002-222707 and EP 1066823. The rejection is traversed because

- (a) JP '721 does not teach potassium ion, and the claimed amount of potassium ion;
- (b) the combination of JP '721 and EP '823 is impermissible; and
- (c) the claimed oral preparation provides an advantageous result.

The advantageous effect of the claimed oral preparation is that a small amount of calcium phosphate that is present in a small gap between enamel rods of the teeth is turned into fluoride-containing fine particles to form a light scattering layer *inside* enamel which causes an irregular reflection in response to the incident light radiated from the outside. See pages 1-3 of the present specification. Normally, internal discoloration of the teeth is apparent through transparent enamel of the teeth. However, this light scattering layer, which looks white and opaque, shields the yellowish color of the teeth and gives the teeth a white appearance. *Id.* The factors responsible for forming the light scattering layer include, e.g., the components (A), (B) and (C), and a specified pH condition, e.g., see page 10 of the present specification. As shown in the Examples and Comparative Examples of Example B series and

Example C series of the present specification, the light scattering layer is not formed when any of the components (A), (B) and (C) is not included.

The present specification addresses the disclosure of JP '721 and describes that the oral preparation of JP '721 forms a layer of calcium fluoride on a surface of the teeth to provide whiteness and gloss (pages 2-3, the bridging paragraph). The composition of JP '721 is used for whitening the surface of the teeth, wherein the exogenous coloring matter adheres to a tooth when a person eats, drinks, e.g., coffee or tea, smokes, etc. ([0002]).

The oral preparation of JP '721 comprises a source of fluoride and an organic acid. However, JP '721 does not describe or suggest adding potassium ion. In fact, a potassium ion supplying compound is not used in the Examples of JP '721. Also, JP '721 fails to describe the amount of potassium ion so that a light scattering layer can be formed.

The composition of JP '721 is similar to the composition of the Comparative Examples in Tables B1-B3 of the present specification which do not comprise potassium ion and do not form a light scattering layer inside a tooth, as described on pages 33-34 of the present specification.

The addition of potassium ion, as in the Inventive Examples in Tables B1-B3, provides the formation of an internal light scattering layer which makes teeth whiter.

More specifically with regard to the Examples provided in the present specification, Tables A1-A5 describe different amounts of potassium ion (in addition to 0.13 mol/kg referred to in the Advisory Action). Also, the claimed organic acid is malic and/or tartaric acid, i.e., the organic acids used in the Examples.

Thus, the claimed oral preparation provides an advantageous result for the full scope of the claims.

The Office has agreed that JP '721 does not teach potassium ion (the OA, page 3) and relied on EP '823 describing a bleaching composition in which potassium ion is added as a

desensitizer ([0011]). The Office is of the opinion that adding potassium ion as a desensitizer to the surface whitening composition of JP '721 would have been obvious and would have provided an expected result, e.g., whitening and desensitizing.

(A) In response, it is noted that introducing potassium ion of EP '823 into the whitening composition of JP '721, which provides a gradual formation of calcium fluoride on the surface of the teeth (see [0006]), changes the formation of the surface calcium fluoride layer to the formation of an internal light scattering layer, as demonstrated in the present specification. Thus, the goal of JP '721 of the gradual formation of calcium fluoride on the surface of the teeth cannot be realized with the modification by potassium ion and, therefore, the combination of JP '721 and EP '823 is impermissible.

(B) EP '823 and JP '721 do not describe or suggest that when the oral preparation is applied to the teeth, wherein an endogenous colored substance is deposited in the depth of the enamel, a light scattering layer that masks the deposited endogenous colored substance is formed inside the enamel of the teeth. More specifically, when the claimed oral preparation is applied to the teeth, fluoride-containing fine particles enter a small gap between enamel rods to form a light scattering layer which causes an irregular reflection in response to the incident light radiated from the outside, and as a result, the endogenous colored substance deposited inside the enamel is masked by the light scattering layer which looks white and opaque. Thus, the teeth look white without removing the endogenous colored substance. A person skilled in the art would not have reasonably expected such an advantageous effect based on the disclosure of the cited references.

(C) The composition disclosed in EP '823 is a dental bleaching composition which comprises carbamide peroxide as an essential component. Carbamide peroxide is an unstable substance. As described in paragraph [0028] of EP '823, carbamide peroxide is unstable when water is previously mixed with the composition, and the composition has to be mixed

with water at the time of using the composition. In addition, carbamide peroxide cannot stably exist in compositions at a pH 3 to 5.5. EP '823 does no description using an acid; the compositions of EP '823 are neutral and all of the bleaching agents used in the Examples are also neutral.

In contrast, the compositions of JP '721 are acidic and have a pH 3-5.5.

The bleaching agent of EP '823 and the oral composition of JP '721 have very different pH ranges, and the pH of the agent of EP '823 and the composition of JP '721 were adjusted to specific ranges to fulfill different goals specific to each of EP '823 and JP '721. Therefore, a skilled artisan would not have been motivated to combine various components of the bleaching agent of EP '823 and the oral composition of JP '721 that have very different pH ranges with a reasonable expectation of improving (or preserving) the properties of the oral composition of JP '721. Thus, the claimed oral preparation which has a pH 3-5.5 and comprises a specific acid, specific fluoride ion supplying compound, potassium ion and water as essential components, would not have been obvious over JP '721 and EP '823.

(D) Further, by using a large amount of potassium ion (C), the claimed oral preparation and method allow promoting the formation of a light scattering layer inside the enamel of the teeth and decreasing the amount of (B) to 0.03 to 0.5 mol/kg (e.g., in the Examples of the present specification, the upper limit is 0.15 mol/kg). As a result of the decreased amount of (B), the composition has good flavor. This result would not have been obvious based on the disclosure of the cited references. JP '721 does not describe using a large amount of (C) and uses a large amount of (B), i.e., 0.1-5 mol/kg (0.4-1.5 mol/kg in the Examples).

The claimed oral preparation provides an advantageous result and the mechanism of the formation of a light scattering layer when potassium ion is added is described on page 15, line 19 to page 17, line 5 of the present specification.

In addition, JP '721 addresses diminishing sensitivity of teeth in the Examples, e.g., paragraph [0028] and Tables 1-3 (please, see [0034] of **US 2003/0124068** as an English equivalent). It is described that the composition of Examples 3-1 – 3-4 when used for one month provided the alleviation of pain which was sensed upon drinking cold water.

Thus, a skilled artisan would not have been motivated to introduce a desensitizer of EP '823 in the composition of JP '721 which already alleviates pain sensed upon drinking cold water.

Thus, EP '823 and JP '721 do not make the claimed oral preparation obvious.

Applicants request that the obviousness rejection be withdrawn.

A Notice of Allowance for all pending claims is requested.

Respectfully submitted,

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